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Original article

Does cross-linked polyethylene decrease the revision rate of total hip arthroplasty compared with conventional polyethylene? A meta-analysis

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ABSTRACT

Background: Although cross-linked polyethylene is resistant to wear in comparison to conventional polyethylene, it remains unknown whether it can decrease the wear-related revision rate of total hip arthroplasty.
Objectives: To determine whether cross-linked polyethylene decreases the wear-related revision rate of total hip arthroplasty compared with conventional polyethylene.
Data sources: Electronic databases, including PubMed, EMBASE, and the Cochrane Central Register of Controlled Trials, were queried from inception to July 6, 2013.
Study selection: Randomized controlled trials (RCTs) comparing cross-linked polyethylene with conventional polyethylene were included. In addition, the standard 28-mm femoral head was used, and follow-up was performed for a minimum of 5 years. The primary outcome assessed was wear-related revision. The secondary outcome measures evaluated were the incidence of osteolysis, the linear wear rate, and the linear head penetration.
Data synthesis: The Cochrane Collaboration's tool for assessing the risk of bias was used for quality assessment. Data from eligible studies were pooled using a random effects model.
Results: Eight studies involving 735 patients were included in this study. Meta-analysis showed there was no significant difference between cross-linked and conventional polyethylene group in terms of osteolysis or wear-related revision. The pooled mean differences were significantly less for the linear wear rate and linear head penetration for cross-linked polyethylene than for conventional polyethylene.
Limitations: The studies differed with respect to the cross-linked liner brands, manufacturing processes, and radiological evaluation methods. Moreover, the follow-up periods of the RCTs were not long enough.
Conclusions: The current limited evidence suggests that cross-linked polyethylene significantly reduced the radiological wear compared with conventional polyethylene at midterm follow-up periods. However, there is no evidence that cross-linked polyethylene had an advantage over conventional polyethylene in terms of reducing osteolysis or wear-related revision. Nevertheless, future long-term RCTs on this topic are needed.
Key findings: Cross-linked polyethylene significantly reduced radiological wear but not osteolysis or wear-related revision in comparison to conventional polyethylene at midterm follow-up periods.
Level of evidence: Level I, systematic review of level I studies.

1. Introduction

Although total hip arthroplasty (THA) has provided satisfactory results for over four decades, the optimal bearing surface remains controversial. Hard bearing surfaces such as ceramic-on-ceramic (CoC) and metal-on-metal (MoM) have outstanding wear performance [1,2], but they have their own inherent limitations and may not be suitable for all patients. CoC bearings have been documented to squeak or fracture catastrophically [3,4]. MoM bearings have been associated with increased metal ion levels in serum [5]. Metal-on-polyethylene bearings have been used as the main material for contact surfaces in THA; however, the survivorship has been limited by aseptic loosening and osteolysis secondary to wear and particulate polyethylene debris [6,7].

To reduce the volume of wear debris generated at the bearing surface and thereby improve the longevity of the prosthesis, several

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changes in the manufacturing process for conventional polyethylene have been instituted over the last two decades. The most relevant modification has been the use of irradiation with an electron beam or with gamma radiation to increase the number of cross-links between the polymer chains [8–10]. The resulting materials are known as cross-linked polyethylenes.

In vitro analysis has shown that cross-linked polyethylene has a greatly increased resistance to wear in comparison to conventional polyethylene [10,11]. Similarly, some randomized controlled trials (RCTs) have shown that the use of cross-linked polyethylene leads to less wear than the use of conventional polyethylene [12–15]. As most of these studies had short-term follow-ups, it remains unknown whether these improvements result in less aseptic loosening and improved implant longevity in the long-term. Several systematic reviews have compared cross-linked and conventional polyethylenes [16–18]. The weakness of these studies is the inclusion of short-term trials, thereby compromising the ability to gain information on wear-related revision outcomes. Recently, several RCTs with midterm (five-to-ten-year) and long-term (more than ten-year) follow-ups have been published [19–22].

In light of these issues, the present meta-analysis of data from RCTs aimed to provide an evidence-based appraisal of the effects of cross-linked polyethylene compared with conventional polyethylene in patients who underwent THA. We postulated that cross-linked polyethylene demonstrates a lower incidence of wear-related revision at midterm to long-term follow-up compared with conventional polyethylene.

2. Methods

2.1. Data sources and searches

Electronic databases, including PubMed, EMBASE, and the Cochrane Central Register of Controlled Trials, were queried for search terms in the following format: (arthroplasty, replacement, hip [mh] or total hip arthroplasty or total hip replacement or THA OR THR) and (cross-linked or cross-linked or cross-linking). Reference lists of relevant articles were manually searched for additional trials. The search was not restricted by language. The latest date for this search was July 6, 2013.

2.2. Inclusion criteria

Studies eligible for inclusion met the following criteria:

- RCT;
- patients underwent THA;
- both cross-linked and conventional polyethylene liners were included;
- only the standard 28-mm femoral head was used;
- reported wear-related revision outcome;
- follow-up was performed for a minimum of 5 years.

All studies that did not meet these criteria were excluded.

2.3. Data extraction and outcome measures

Two reviewers independently extracted data using a standardized extraction form. Disagreements were resolved by discussion until consensus was reached. In the case that the two reviewers could not reach a consensus, a third reviewer was asked for a final opinion, resulting in a group consensus. The primary outcome assessed was wear-related revision. Secondary outcome measures were the incidence of osteolysis, the linear wear rate, and the linear head penetration. These outcome measures were chosen because they were included in most studies.

2.4. Quality assessment

The Cochrane Collaboration's tool for assessing the risk of bias was used for quality assessment [23]. This tool focuses on seven criteria:

- sequence generation;
- allocation concealment;
- blinding of participants and personnel;
- blinding of outcome assessment;
- incomplete outcome data;
- selective outcome reporting;
- other sources of bias.

Each RCT was classified as "low risk" "high risk" or "unclear risk" for each criterion.

2.5. Statistical analysis

For dichotomous outcomes, the risk difference (RD) and 95% confidence interval (CI) were calculated as the summary statistics. For continuous outcomes, data means and standard deviations (SDs) were used to calculate a weighted mean difference (WMD) and 95% CI in the meta-analysis. Heterogeneity between studies was quantified using the I^2 statistic. An I^2 value of 0% represents no heterogeneity, and values of 25%, 50%, and 75% or more represent low, moderate, and high heterogeneity, respectively [24]. Data from eligible studies were pooled using a random effects model because of the anticipated heterogeneity among study populations, follow-up durations, implant brands, manufacturing processes, and radiological evaluation methods. A sensitivity analysis was performed to explore possible explanations for heterogeneity. A P-value < 0.05 was judged as statistically significant, except where otherwise specified. All statistical tests were performed with Review Manager (Version 5.1, The Cochrane Collaboration).

3. Results

3.1. Literature search

Of the 961 potentially relevant studies identified through the literature search (Fig. 1), 38 studies were retrieved for

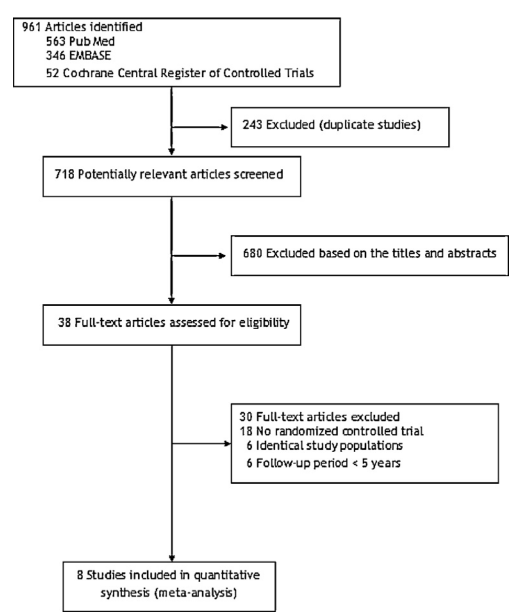

Fig. 1. Flow diagram of the study with a summary of the search process. Seven studies were included in the final analysis.

Table 1
Study characteristics.

Study	Treatment groups	No. of hips	Mean age (y)	% Male	BMI or weight	Follow-up (y)
Engh et al., 2012 [19]	Cross-linked PE (Marathon, DePuy)	116	62.5 (26 to 87)	44	28.6 (19.9 to 47.3)	10.0 ± 1.8
	Conventional PE (Enduron, DePuy)	114	62.0 (34 to 84)	50	27.9 (19.6 to 47.9)	
Johanson et al., 2012 [21]	Cross-linked PE (Durasul, Zimmer)	25	55 (42 to 68)	48	82 kg (47 to 116)	10
	Conventional PE (Sulene, Zimmer)	27	56 (41 to 70)	44	83 (58 to 120)	
Garcia-Rey et al., 2012 [20]	Cross-linked PE (Durasul, Zimmer)	42	67.4 (47 to 78)	43	74.1 kg (55 to 108)	10 to 12
	Conventional PE (Sulene, Zimmer)	41	61.1 (25 to 78)	46	75.1 kg (52 to 106)	
Thomas et al., 2011 [22]	Cross-linked PE (Longevity, Zimmer)	22	68 (52 to 76)	45	79 kg (49 to 117)	7
	Conventional PE (Zimmer)	22	67 (51 to 76)	50	82 kg (75 to 108)	
Mutimer et al., 2010 [25]	Cross-linked PE (Marathon, DePuy)	55	62 (46 to 75)	64	Not available	5
	Conventional PE (Enduron, DePuy)	55	61 (48 to 75)	47	Not available	
McCalden et al., 2009 [26]	Cross-linked PE (Longevity, Zimmer)	50	72.3 (56 to 79)	34	29.7 (22 to 39)	6.8
	Conventional PE (Trilogy, Zimmer)	50	72.6 (56 to 79)	28	29.71 (18 to 48)	
Geerdink et al., 2009 [27]	Cross-linked PE (Duration, Stryker)	22	64 (48 to 74)	65	28 (24 to 36)	8
	Conventional PE	26	64 (54 to 72)	57	28 (23 to 49)	
Nikolaou et al., 2012 [28]	Cross-linked PE (Smith & Nephew)	32	55.1 (41 to 64)	44	32.6 (21.8 to 45.5)	5
	Conventional PE (Smith & Nephew)	36	52.6 (20 to 64)	50	28.7 (19.2 to 41.2)	

PE: polyethylene; BMI: body mass index.

Table 2
Risk of bias in included studies.

Study	Random sequence generation	Allocation concealment	Blinding of participants	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Enhg et al., 2012 [19]	Unclear risk	High risk	Unclear risk	Low risk	Low risk	Low risk	Unclear risk
Tomas et al., 2011 [22]	Low risk	Unclear risk	Low risk	Unclear risk	Low risk	Unclear risk	Unclear risk
Garcia-Rey et al., 2012 [20]	Low risk	High risk	Unclear risk	Unclear risk	Low risk	Low risk	Unclear risk
Mccalden et al., 2009 [26]	Unclear risk	High risk	Low risk	Low risk	Low risk	Unclear risk	Unclear risk
Geerdink et al., 2009 [27]	Low risk	High risk	High risk	Unclear risk	High risk	Low risk	Unclear risk
Mutimer et al., 2010 [25]	Unclear risk	Low risk	Low risk	Low risk	Low risk	Unclear risk	Unclear risk
Johanson et al., 2012 [21]	High risk	Low risk	High risk	High risk	Low risk	Low risk	Unclear risk
Nikolaou et al., 2012 [28]	Low risk	Unclear risk	High risk	Low risk	Low risk	Low risk	Unclear risk

full-text assessment, and eight studies met our inclusion criteria [19–22,25–27]. Of these studies, 30 were excluded for the following reasons: 18 studies were not RCTs, six studies dealt with identical study populations, and six studies had a follow-up period < 5 years.

3.2. *Study characteristics*

The main characteristics of the eight RCTs included in the meta-analysis are presented in Table 1. The risk of bias results for the studies is summarized in Table 2. These studies were published between 2009 and 2012. The size of the RCTs ranged from 44–230 subjects (total 735). All eight of the studies reported wear-related revision events, five reported osteolysis events, four evaluated the linear wear rate, and four included the linear head penetration.

3.3. *Primary outcome: wear-related revision*

Meta-analysis of the wear-related revision incidence showed there was no significant difference between the cross-linked and conventional polyethylene groups (RD, −0.02, 95% CI, −0.05 to 0.01; $P = 0.20$; Fig. 2), and there was moderate heterogeneity ($I^2 = 52\%$). Subsequently, we performed sensitivity analyses to explore the potential source of heterogeneity. Exclusion of the study by Engh et al., [19] which had a high revision rate in the conventional polyethylene group, resolved the heterogeneity but did not change the results (RD −0.01, 95% CI −0.03 to 0.01; $P = 0.54$; $I^2 = 0\%$). Further exclusion of any single study did not materially alter the heterogeneity, which ranged from 57% to 62%.

3.4. *Secondary outcomes*

3.4.1. *Osteolysis*

Meta-analysis of the incidence of osteolysis showed there was no significant difference between the cross-linked and conventional polyethylene groups (RD, −0.12; 95% CI, −0.26 to 0.03; $P = 0.12$), and there was high heterogeneity ($I^2 = 92\%$; Fig. 3). Exclusion of any single study did not materially alter the heterogeneity, which ranged from 83% to 95%.

3.4.2. *Linear head penetration*

Meta-analysis of linear head penetration showed a difference favoring the cross-linked polyethylene over the conventional polyethylene (WMD, −0.07; 95% CI, −0.13 to −0.01; $P = 0.02$), and there was high heterogeneity ($I^2 = 94\%$; Fig. 4). Exclusion of the trial conducted by Engh et al. [19] resolved the heterogeneity but did not change the results (WMD, −0.05; 95% CI, −0.06 to −0.03; $P < 0.001$; $I^2 = 0\%$). Further exclusion of any single study did not materially alter the high heterogeneity, which ranged from 94% to 96%.

3.4.3. *Linear wear rate*

The linear wear rate was lower in the cross-linked polyethylene group than in the conventional polyethylene group (WMD, −0.09; 95% CI, −0.15 to −0.03; $P = 0.006$), with high heterogeneity ($I^2 = 95\%$) (Fig. 5). Further exclusion of any single study did not materially alter the heterogeneity, which ranged from 78% to 96%.

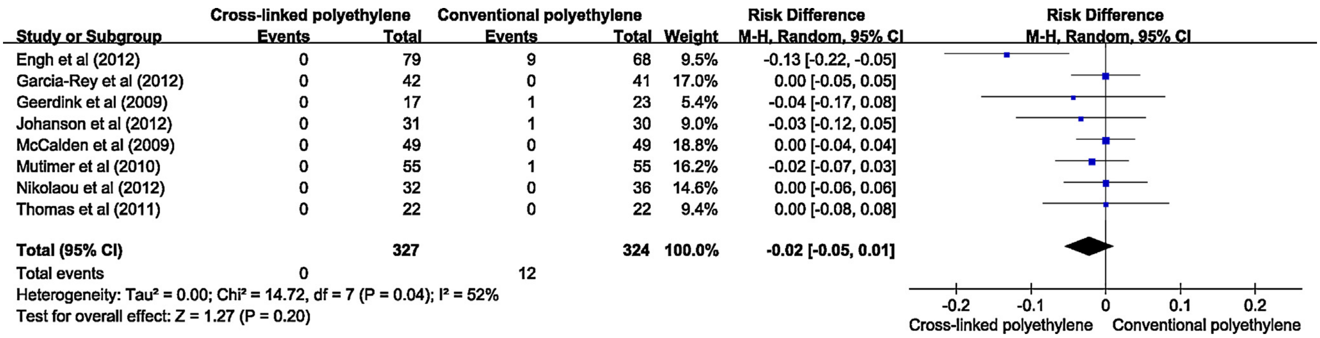

Fig. 2. Forest plot of wear-related revision. M-H, Mantel-Haenszel statistical method.

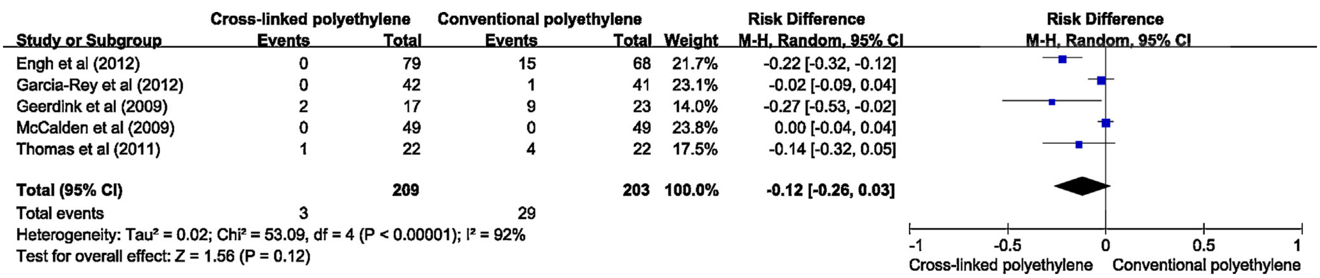

Fig. 3. Forest plot of osteolysis. M-H, Mantel-Haenszel statistical method.

3.5. Publication bias

Fig. 6 shows a funnel plot for studies reporting the RD of wear-related revision as a measure of the treatment effect. The plot is symmetrical, so there is minimal evidence of publication bias. Because of the limited number (< 10) of studies included in this meta-analysis, this result should be interpreted with caution.

4. Discussion

Several review articles have compared cross-linked and conventional polyethylene. One systematic review [17] published in 2009 examined data on radiographic outcomes; however, the researchers did not statistically pool the data to compare treatment effects. Another article [18] published in 2011 reviewed data from several cohort studies and RCTs, and it examined wear and osteolysis, but it did not document the revision outcome. One previous meta-analysis [16] published in 2011 found that using cross-linked polyethylene led to a significant reduction in radiological wear and in the incidence of osteolysis compared to the use of conventional polyethylene, but the rates of revision were not significantly different between the two groups. However, this meta-analysis included short-term and midterm studies, and these follow-up periods may not have been long enough.

In this meta-analysis of RCTs with midterm to long-term follow-ups, we found that cross-linked polyethylene significantly reduced the radiological wear compared to conventional polyethylene. The pooled mean differences were significantly less for the linear wear rate and linear head penetration for cross-linked polyethylene compared to conventional polyethylene. These results were consistent with those of previous systematic reviews [16–18]. In this meta-analysis, although each of the four RCTs with linear wear rate

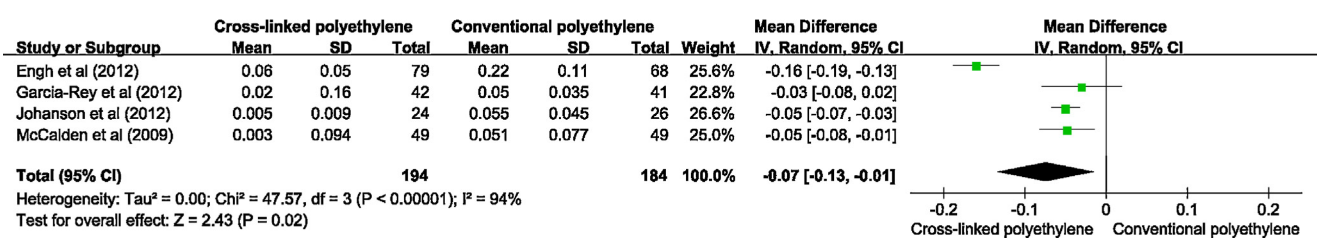

Fig. 4. Forest plot of linear head penetration. IV, inverse variance statistical method.

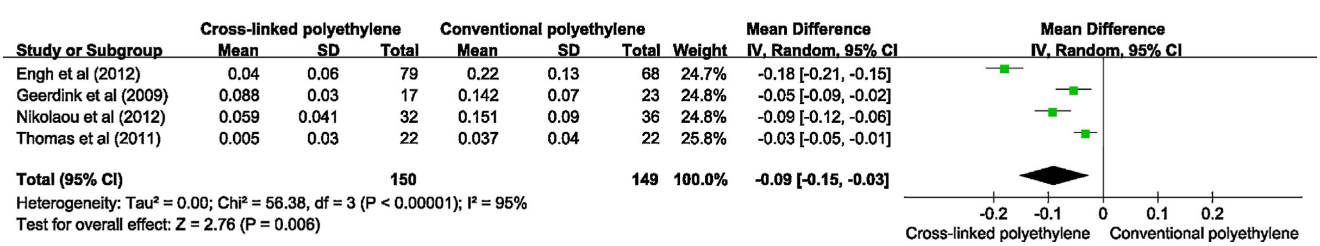

Fig. 5. Forest plot of the linear wear rate. IV, inverse variance statistical method.

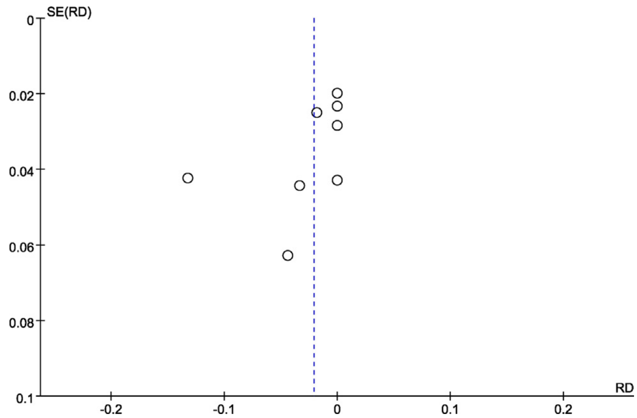

Fig. 6. Funnel plot for the outcome of wear-related revision.

data reported a significant reduction in linear wear rate, there was a high heterogeneity (I^2 = 95%). We speculate that the heterogeneity imparted by these studies results from the different software used for measurement, as one study used the Martell Hip Analysis Suite software, one employed the Roman V 1.70 software, one used EndoMap version 2.01, and one study did not report the software used.

In an in vitro study, Ingram et al. [29] examined the wear rate of non-cross-linked polyethylene and polyethylene cross-linked with 5 or 10 Mrad of gamma irradiation and found that the wear rate of the materials decreased as the level of cross-linking increased. In studies of standard 28-mm heads, some authors have reported that linear wear rates greater than 0.2 mm per year always produce wear particle-induced osteolysis, whereas wear particle-induced osteolysis is mostly absent for annual wear rates less than 0.05 to 0.1 mm per year [6,30–32]. Therefore, these authors suggested that the incidence of osteolysis increases as the rate of wear increases, and osteolysis was significantly associated with prosthesis loosening and revision [6,30–32]. However, several investigators have found that cross-linked polyethylene debris is smaller and more inflammatory than non-cross-linked polyethylene [29,33]. These investigators found that the inflammatory response to polyethylene particles was affected by the degree of cross-linking, and polyethylene cross-linked at 10 Mrad resulted in more osteolysis than non-cross-linked polyethylene. These results suggest that the improved wear characteristics of highly cross-linked polyethylene may be offset somewhat by the modestly increased inflammatory profile of the highly cross-linked particles compared with the non-cross-linked particles. Our meta-analysis showed that cross-linked polyethylene yields a significantly improved wear in comparison to conventional polyethylene; however, these wear advantages did not translate into less osteolysis or aseptic loosening. These results contradicted our hypothesis. It is possible that differences in particle size and inflammatory response affect the predicted improvement in outcome after THA.

The association between the femoral head size and the linear wear rate or osteolysis remains unclear. A clinical study by Hammerberg et al. [34] demonstrated that there was no statistical difference in linear wear rates and the annual or total penetration rates when 28-mm and 32-mm heads were compared to 38-mm and 44-mm heads. In a midterm follow-up study, Lachiewicz et al. [35] found no association between femoral head size and the linear wear rate, but observed associations between larger (36- and 40-mm) head size and the volumetric wear rate and the total volumetric wear. In contrast, a comparative study by Tarasevicius et al. [36] indicated that over a 10-year follow-up, wear was greater for the larger femoral head, which was correlated with capsular distension. Similarly, a systematic review by Cross et al. [37] suggests that volumetric wear increases with large femoral heads on polyethylene and increases corrosion of the stem in large metal-on-metal modular THA; however, the risk of potentially developing osteolysis or adverse reactions to metal debris is still unknown. In this meta-analysis, we exclusively included the THA with the standard 28-mm head size to avoid the possible confounding effect associated with different head sizes.

Some authors have raised concerns about the effects of cross-linking on the mechanical properties of highly cross-linked polyethylene, which has a lower toughness and elastic modulus than conventional polyethylene [38]. However, none of the RCTs included in our study documented liner rupture events, indicating the safety of cross-linked polyethylene.

The studies involved in the meta-analysis were relatively small, which compromised the ability to draw strong conclusions. The strength of this meta-analysis is the exclusive analysis of RCTs, which helped to reduce the systematic error inherent in retrospective and some prospective cohort studies. A meta-analysis is most persuasive when data from RCTs are pooled.

This meta-analysis has several potential limitations that should be taken into account. The studies differed with respect to the cross-linked liner brands, manufacturing processes, and radiological evaluation methods, which may have a potential impact on our results. In addition, conflict of interest is an issue that requires special consideration. In this review, we were not sure whether the authors of the eight studies received benefits from commercial parties or not. Some investigators have reported that research is more likely to favor a product when an investigator has a financial interest in or funding from the company that manufactures the product [39]. Moreover, the follow-up periods of the RCTs ranged from 5–12 years, and the revision rates may change with longer follow-ups. Future reports with longer follow-ups in the next few years will provide a more accurate reflection of revision rates.

5. Conclusions

The current limited evidence suggests that cross-linked polyethylene significantly reduced the radiological wear compared with conventional polyethylene at midterm follow-up periods. However, these results contradicted our hypothesis that cross-linked polyethylene has an advantage over conventional polyethylene in terms of reducing osteolysis or wear-related revision. Nevertheless, future long-term RCTs on this topic are needed.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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